K083518

510(k) Summary

MAR 1 3 2009

Applicant Contact Information:

Applicant:	Instrumentation Laboratory Co.
Address:	113 Hartwell Avenue Lexington, MA 02421
Contact Person:	Carol Marble, Regulatory Affairs Director
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Preparation Date:	February 26, 2009

Device Trade Names:

ACL™ AcuStar™

HemosIL™ AcuStar™ D-Dimer

HemosIL™ AcuStar™ D-Dimer Controls

Device Regulatory Information:

Regulation Nos.:	21 CFR 864.7320 (Assay); 21 CFR 864.5425 (Instrument and Controls)
Regulation Names:	Multipurpose System for *In Vitro* Coagulation Studies Fibrinogen and Fibrin Split Products, Antigen, Antiserum, Control (Assay) Plasma, Coagulation Controls (Controls)
Regulatory Class:	Class II
Product Codes:	JPA (Instrument), DAP (Assay) and GGN (Controls)
Panel:	Hematology

Predicate Devices:

K891385	VIDAS Instrument
K040882	VIDAS D-Dimer Exclusion Assay
K073377	ACL TOP
K070927	HemosIL D-Dimer HS
K972696	HemosIL D-Dimer Controls

Device Indications for Use:

- **ACL AcuStar:** Automated immunoassay analyzer designed specifically for *in vitro* diagnostic use in a clinical laboratory. The assay analysis is based on chemiluminescent technology. The system provides results for both direct measurements and calculated parameters.

- **HemosIL AcuStar D-Dimer:** Fully automated chemiluminescent immunoassay for the quantitative determination of D-Dimer in human citrated plasma on the ACL AcuStar as an aid in the diagnosis of venous thromboembolism (VTE) [deep vein thrombosis (DVT) and pulmonary embolism (PE)].

- **HemosIL AcuStar D-Dimer Controls:** For the quality control of D-Dimer assay performed on the ACL AcuStar.

510(k) Summary (Cont.)

Device Descriptions:

- **ACL AcuStar:**

  The AcuStar is an automated, bench-top system for lab use that measures the analyte amount in blood samples by:

  - Subjecting the blood sample to reagents that cause a reaction with an antigen or antibody in the sample.
  - Placing the cuvettes in a controlled environment to allow the reactants to bind into a complex.
  - Separating out the complex from unused reactants.
  - Treating this complex with a chemical that produces light in proportion to the analyte concentration.
  - Measuring the light output to determine the amount of antibodies or antigens that were in the sample.

- **HemosIL AcuStar D-Dimer:**

  The HemosIL AcuStar D-Dimer assay is a two-step immunoassay to quantify D-Dimer in human citrated plasma using magnetic particles as solid phase and a chemiluminescent detection system. In the first step, sample, anti-D-Dimer antibody coated magnetic particles, and assay buffer are combined, and the fibrin soluble derivatives containing the D-Dimer domain present in the sample bind to the anti-D-Dimer antibody coated magnetic particles. After magnetic separation and washing, an anti-XDP antibody labeled with isoluminol is added and incubated in a second step. After a new magnetic separation and washing, two triggers are added and the resulting chemiluminescent reaction is measured as relative light units (RLUs) by the ACL AcuStar optical system. The RLUs are directly proportional to the D-Dimer concentration in the sample. The ACL AcuStar D-Dimer assay utilizes a 4 Parameter Logistic Curve (4PLC) fit data reduction method to generate a Master Curve. The Master Curve is predefined lot dependent, and is stored in the instrument through the cartridge barcode. With the measurement of calibrators, the predefined Master Curve is transformed to a new, instrument specific 4PLC Working Curve. The concentration values of the calibrators are included in the calibrator plastic tube barcodes.

- **HemosIL AcuStar D-Dimer Controls:**

  The Low, High, and Very High D-Dimer Controls are prepared by means of a dedicated process and contain different concentrations of partially purified D-Dimer obtained by digestion of Factor XIIIa cross-linked human fibrin with human plasmin.

510(k) Summary (Cont.)

Substantial Equivalence:

Differences and Similarities	New Device: ACL AcuStar and HemosIL AcuStar D-Dimer and HemosIL AcuStar D-Dimer Ctrls	Predicate Devices: ACL TOP (K073377) with HemosIL D-Dimer HS (K070927) and HemosIL D-Dimer Controls (K972696)	Predicate Devices: VIDAS Instrument (K891385) with VIDAS D-Dimer Exclusion Assay (K040882)
Indications for Use	Fully automated chemiluminescent immunoassay for the quantitative determination of D-Dimer in human citrated plasma on the ACL AcuStar as an aid in the diagnosis of venous thromboembolism (VTE) [deep vein thrombosis (DVT) and pulmonary embolism (PE)].	Automated latex enhanced immunoassay for the quantitative determination of D-Dimer in human citrated plasma on the ACL TOP Family Systems for use in conjunction with a clinical pretest probability (PTP) assessment model to exclude venous thromboembolism (VTE) in outpatients suspected of deep venous thrombosis (DVT) and pulmonary embolism (PE).	Automated quantitative test for use on the VIDAS analyzers for the immunoenzymatic determination of fibrin degradation products (FbDP) in citrated human plasma using the ELFA techniques (Enzyme Linked Fluorescent Assay). The VIDAS D-Dimer Exclusion assay is indicated for use in conjunction with a clinical Pre-test Probability (PTP) assessment model to exclude deep venous thrombosis (DVT) and pulmonary embolism (PE) in outpatients suspected of DVT and PE.
Physical Format	Single cartridge containing reagents	Lyophilized Latex Reagent	Ready-to-use strips
Assay Principle	Two-step chemiluminescent immunoassay	Latex-enhanced immunoturbidmetric assay	Two-step enzyme immunoassay sandwich method with a final fluorescent detection
Instrument Platform	ACL AcuStar	ACL TOP family of analyzers	VIDAS instruments
Sample Type	Citrated Plasma	Same	Same
Calibrator	D-Dimer Calibrator (included in kit)	D-Dimer Calibrator (included in kit)	D-Dimer Calibrator (included in kit)
Quality Controls	AcuStar D-Dimer Controls, Low, High and Very High (sold separately)	HemosIL D-Dimer Controls, Low and High (sold separately)	D-Dimer Controls (included in kit)
Detection Limit	6.51 ng/mL	21 ng/mL	45 ng/mL (FEU)
Linear Range	54.3 – 1110000 ng/mL with Auto Rerun	150 - 69000 ng/mL with Auto Rerun	45-10000 ng/mL (FEU)
Clinical Cut-off	500 ng/mL (FEU)	230 ng/mL (D-Dimer Units)	500 ng/mL (FEU)

510(k) Summary (Cont.)

Summary Performance Data:

Precision

Precision was assessed over multiple runs using the three levels of HemosIL AcuStar D-Dimer Controls and the kit Calibrator Level 1 on an ACL AcuStar instrument:

ACL AcuStar	Mean (ng/mL)	CV% (Within run)	CV% (Total)
Low D-Dimer Control	234	4.0%	6.8%
High D-Dimer Control	841	2.3%	4.9%
Very High D-Dimer Control	8467	2.5%	5.6%
Calibrator 1	358	2.7%	5.4%

Method Comparison

An in-house method comparison study was performed to compare the performance of HemosIL AcuStar D-Dimer on an ACL AcuStar versus the VIDAS D-Dimer Exclusion Assay with the following results:

n	Slope	r
179	1.16	0.888

Management Study

A management study was performed on 344 frozen citrated plasmas from patients admitted to an emergency unit with suspected PE or DVT (frequency of venous thrombosis disease 28.2%). Of the 344 samples, 97 were confirmed as VTE positive (64 PE and 33 DVT) by standard objective tests and the remaining 247 were confirmed as negative.

Instrument	N	Cut-off	% Sensitivity (95% CI)	% Specificity (95% CI)	% NPV (95% CI)
ACL AcuStar	344	500 ng/mL	100% (96.3%-100.0%)	55.5% (49.0%-61.8%)	100% (97.3%-100.0%)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 3 2009

Instrumentation Laboratory Co.
c/o Ms. Carol Marble
Regulatory Affairs Director
113 Hartwell Avenue
Lexington, MA 02421

Re: k083518
Trade/Device Name: ACL™ AcuStar™, HemosIL™ AcuStar™ D-Dimer and HemsIL™ AcuStar™ D-Dimer Controls
Regulation Number: 21 CFR 864.7320
Regulation Name: Fibrinogen/Fibrin Degradation Product Assay
Regulatory Class: Class II
Product Code: JPA, DAP, GGN
Dated: February 26, 2009
Received: February 27, 2009

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin

marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K083518

Devices Name: ACL™ AcuStar™
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HemosIL™ AcuStar™ D-Dimer Controls

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Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K083518